

Follow-up-Meldungen und Non urgent Informationen (NUI)

Follow-up (in this case concerning verified falsifications)

Bezirksregierung Köln Zeughausstr. 2-10 D-50667 Köln	
1. To: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	
2. Recall Number Assigned: FTS2019-010/H/Xarelto/Falsification	2a. National reference number (When applicable)
4. Product: Xarelto 20 mg, 28 tablets (Rivaroxaban tablets)	5. Marketing Authorisation number: EU/1/08/472/018 for use in humans
6. Brand/Trade name: Xarelto	7. INN or Generic Name: Rivaroxaban
8. Dosage form: tablets	9. Strength: 20mg
10. Batch number (and bulk, if different): BXHUBD2 BXHXL41 BXHVHC3 (already reported on May 25 th)	Expiry date of all 3 batches: Sept. 2020
14. Marketing Authorisation holder: Bayer AG Leverkusen	
15. Manufacturer ¹ : Original product: Bayer AG Leverkusen	16. Contact Person: Dr. Büllersbach Telephone: +49 214 3046227
17. Subject title Important Update FTS2019-010/H/Xarelto/Falsification - Information about 2 additional falsified batches of Xarelto® 20mg (Rivaroxaban, 28 tablets)	

¹ The holder of an authorisation to under Article 40 of Directive 2001/83/EC and Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC, if different

22. From (issuing Authority): Bezirksregierung Köln Zeughausstr. 2-10 50667 Köln mail to: AstridBettina.Meiser@bezreg-koeln.nrw.de		23. Contact person: Astrid Meiser Telephone: +49 (0) 221 1472128 Deputy: Roland Pietz Telephone: +49 (0) 221 1472540	
24. Signed: A. Meiser		25. Date: June 13 th 2019	26. Time: 14:45